APR 19 2005

K050165

7. Summary Statement

1. General Information

Submitter: Cyden Ltd
Technium
Kings Road, The Docks
Swansea,
Wales, UK, SA1 8PH

Contact Person: Dr Mike Kiernan – Director of Clinical Research

Summary Preparation Date: 14th January 2005

2. Names

Device Name: IFL Professional System

Primary Classification Name: Laser Powered Surgical Instrument

3. Predicate Devices

- Palomar Estelux System, LuxV Handpiece cleared April 2004, 510(k) approval number K040081;
- Radiancy Acne System with ClearTouch cleared December 2003, 510(k) approval number K032205;
- ICN NLite System, cleared June 2003, 510(k) approval number K024189.

4. Product Description

The IFL Professional System is a pulsed Xenon flashlamp delivering energy in the 530 to 1200nm wavelength range. The system consists of a base unit containing the electrical and electronic control subsystems, an umbilical interconnection between the base unit and the handpiece, and the handpiece which houses the xenon light source, filter and finger switch.

5. Indications for Use

The IFL Professional System is indicated for use in Dermatological and Plastic Surgery applications and specifically for long term stable, or permanent, hair reduction.

The IFL Professional System is indicated for the treatment of mild to moderate inflammatory Acne Vulgaris.

6. Rationale for Substantial Equivalence

The IFL Professional system and its predicate devices have the same mode of action and produce the similar output parameters. The Indications for Use of the IFL Professional and the predicate devices are identical, namely the treatment of mild to moderate inflammatory Acne Vulgaris.

7. Safety and Efficacy Information

Not Applicable. Substantial equivalence to the predicate devices is claimed due to identical technological characteristics and intended Indications for Use.

8. Conclusion

The IFL Professional system has been found to be substantially equivalent to the predicate devices, specifically in technological design and operation and similar in nature to the desired physiological interactions. The design and manufacture of the device is in accordance with the relative international standards and the potential risk to operator and patient has been minimized.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 19 2005

Dr. Mike Kiernan
Director of Clinical Research
CyDen Limited
Techium 2, Kings Road
Swansea, Wales
United Kingdom SA1 8PH

Re: K050165
Trade/Device Name:
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: January 14, 2005
Received: January 25, 2005

Dear Dr. Kiernan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

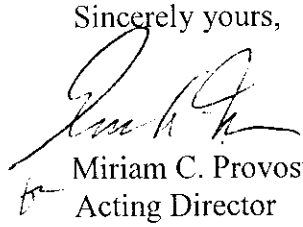
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K050165

510(k) Number (if known): Not Known

Device Name: IFL Professional

Indications For Use:

The IFL Professional System is indicated for use in Dermatological and Plastic Surgery applications and specifically for long term stable, or permanent, hair reduction.

In addition, the IFL Professional System is indicated for the treatment of benign cutaneous vascular lesions and the treatment of benign pigmented lesions.

The IFL Professional is indicated for the treatment of mild to moderate inflammatory Acne Vulgaris.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K050165